EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO PLAINTIFFS: Joy Essman Case No. 2:12-cv-00277 Christine Wiltgen Case No. 2:12-cv-01216 Shirley Walker Case No. 2:12-cv-00873 Julie Wroble Case No. 2:12-cv-00883 Nancy Jo Williams Case No. 2:12-cv-00511	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

GENERAL DEPOSITION OF

GREGORY BALES, M.D.

April 2, 2016

Chicago, Illinois

marked as Exhibit 2 yesterday, but I didn't -- I did not bring copies again.

MR. MORIARTY: I have my copy that he can use, but we can't mark it because it has some notes on it.

MS. THOMPSON: We will just -- can we have Exhibit 2 -- both the Notice and the report, which were Exhibits 1 and 2 yesterday, included in this deposition?

(WHEREUPON, certain documents were marked Bales Deposition Exhibit No. 1, Notice to Take Deposition of Gregory T. Bales, M.D., and No. 2, Defense Expert General Reports of Gregory Bales, M.D.)

BY MS. THOMPSON:

Q. Let's first talk about your experience the treatment, the surgical treatment of stress urinary incontinence. What procedures do you currently perform surgically to treat stress urinary incontinence?

A. So, primarily three, three separate procedures. One being the retropubic or classic TVT, the TVT device that goes behind the pubic

bone. I also do TVT-Obturator slings. And we can talk later if you like about how I differentiate who gets what.

So, I do those two synthetic slings, both the retropubic and an obturator, and increasingly I do more autologous slings. So, that's autologous fascial slings. And we can talk again further about why I -- how I differentiate between all three of those.

But those are the three primary slings I use.

Q. Dr. Bales, when you refer to TVT-Retropubic, are you using TVT in a generic sense or are you referring to the Gynecare TVT device?

A. So, at my primary institution, the University of Chicago, we have the Ethicon product line, the TVTs. So, when I say TVT, I meant in this case that I actually use Ethicon's TVT.

As you mentioned, sometimes that can be more generic and any type of synthetic sling could be called TVT or an obturator sling.

I do have privileges at an outside hospital in Munster, Indiana where I go and they

Q. And how many autologous slings over the course of your career?

A. Well, when I first started, obviously, we didn't have any synthetic slings. So, for the first I guess four years of my career we only did autologous fascial slings and now increasingly we are doing more. I would guess 300, 3 to 400 maybe.

Q. And currently what percentage of your slings, what percentage of your surgical treatments for stress incontinence fall into those three categories, retropubic, TVT-O and autologous, approximately?

A. What percentage?

Q. What percentage in each category currently?

A. Currently.

Q. Roughly.

A. I would say probably a third, a third, a third would be reasonable, a reasonable estimate.

Q. And as far as tracking outcomes and complications, would it -- for your sling treatments, would that be similar to what we discussed yesterday, that the residents may be tracking a certain complication that they are

term, importance?

A. I would guess that, yes, I guess I would say they are similar because not any one complication occurs with such great frequency or tends to be so impactful that I think I would make it more important than the other two.

Q. And when you're talking about the pain discomfort that can occur in the inner thigh, that can be transient or that can be chronic, correct?

A. Yeah, I suppose.

Q. And transient pain in the groin or thigh has been reported in the literature to be as high as 26%. Are you aware of that?

A. Transient you said?

Q. Right.

A. Yeah, I think transient, in my experience, can be even a little bit higher than that.

Most patients after a surgical procedure will experience for a short period of time, as you know, transient discomfort related to the surgery itself. But, yes, so I agree with that.

Q. When you are talking about the relatively low incidence of neuromuscular problems

committed malpractice or done something inappropriate, no.

Q. Okay. And exposure I suppose would be similar to what we discussed with the TVT-Retropubic, correct?

A. Yes. There would be no difference for that complication.

Q. Although I think you would agree with me that with the TVT-O there is a higher risk of perforating the vagina, as we call, buttonholing the vagina with a transobturator sling than there is with a retropubic or do you disagree with that?

A. Well, I -- some people report that. I think, again, it gets back to, you know, being careful with your surgical approach.

As you mentioned, with the obturator approach, the trocars are going more laterally and so the sulcus sort of on each side of the vagina, that comes into play a little bit and so if you're not careful, you can -- yes, you can create a buttonhole.

I think you really -- most surgeons, if they are experienced and are paying particular attention to that, as they should be, that really

shouldn't occur very much. But, yes, it's been reported and can and does occur.

Q. And with the third, the neuromuscular complications, is that a combination of those three factors as well?

Why don't we -- when we talk about the TVT or TVT-O, when I ask about it, unless I specify otherwise, I'm talking about the mesh device itself as well as the procedure to place the mesh because would you agree with me they go hand in hand?

A. I think they do go hand in hand.

Q. Okay. So, part of it would just be where you're going with the space that you're working in in the surgery and part of it would be the mesh itself, correct?

A. I agree completely.

Q. Okay. So, with the neuromuscular complications, are those -- would that also be a combination of factors or can you separate out which of those three it is?

A. Yes. In fact, you I think articulated it better than I might, actually.

I think that, fortunately, first, just to digress a moment, they occur fortunately very

infrequently.

But when patients do have some persistent pain in that location, near the obturator foramen or in the inner thigh area, I think it probably is a combination of having performed the surgery, actually violated that space and placed something in that location and perhaps just the product itself, having a sling material in that location adjacent to those nerves and muscles. And in a very, fortunately, a very small number of patients they sort of have some ongoing feelings and sensation in that location.

Q. And you mentioned that you would have reservations about placing the TVT-O in a young, athletic, slender woman. That certainly wouldn't be the patient's fault if a complication develops with an obturator sling placed in that particular individual.

And I'm not talking about just you, your experience, I'm talking about surgeons in general. That wouldn't be something that you could blame the patient for, right?

A. Yes, I don't think you'd blame the patient if she has pain after that procedure. And

MR. MORIARTY: Objection; form. Go ahead.

I am more bothered about it because it's not a report that he intends to offer and is not in his report. I'm sorry. It's not an opinion he intends to offer and it's not in his report.

MS. THOMPSON: You're right and it was really my curiosity.

BY MS. THOMPSON:

Q. So, you don't have to answer that question if you're not going to offer any opinions regarding that.

A. Okay.

Q. And maybe we could talk about that at another time.

MR. MORIARTY: But in all fairness this is a TVT deposition.

MS. THOMPSON: It's a sling deposition.

MR. MORIARTY: Right.

MS. THOMPSON: I could have --

MR. MORIARTY: Stress urinary incontinence treatment deposition.

MS. THOMPSON: I could have narrowed it to mesh devices for stress incontinence, but I'm going to withdraw that question regardless.

well researched by Dr. Blaivas and his colleagues, for example, 397 citations in the paper?

A. Yeah, I mean, it's a review paper. They are compiling a list of other publications.

We discussed this yesterday. You have to include -- you try to be as comprehensive as you can. But obviously it's not 100 percent comprehensive. There is obviously some literature that's missing. You can't cite every single paper.

But it looks like, as you just mentioned, 390 publications.

Q. Going to page 13, under "Pain," the first sentence under "Pain," "Pain is the most poorly studied complication of SMUS surgery. We found only a few studies that included prospective data collection and/or validated questionnaires assessing pain."

Would you agree with Dr. Blaivas that pain is the most poorly studied complication?

MR. MORIARTY: Objection; form. Go ahead.

BY THE WITNESS:

A. I would agree that pain is a poorly studied complication. I guess I'm not sure it's the most poorly studied, but I would agree that

it's poorly studied, in part because pain is very difficult to study, not I think on the part of the investigators. I think it's just very difficult sometimes to measure pain.

BY MS. THOMPSON:

Q. And I think you actually mentioned that earlier when we were talking about the complications of each device.

On the next page, Dr. Blaivas states, "Chronic disabling pain is one of the most common indications for mesh removal particularly in patients fitted with TOT slings."

And I think by that he means transobturator slings generally speaking, would you agree?

First of all, would you agree that that's what he means by TVT and TVT-O would be one of the TVT slings?

A. I would agree with that.

Q. Would you also agree with that statement?

MR. MORIARTY: Objection. Go ahead.

BY MS. THOMPSON:

Q. That chronic disabling pain is one of

the most common indications for mesh removal.

MR. MORIARTY: Objection. Go ahead.

BY THE WITNESS:

A. I would agree that pain is one of the common indications for mesh removal. Again, I personally don't know if it's the most common or -- but sure.

BY MS. THOMPSON:

Q. I think he says one of the most common.

A. I would agree with that.

Q. Let's go to the section beginning on page 15, "Tissue responses to mesh," and I'm happy to give you a little time with each of these questions if you actually want to review that section because I don't expect you to have this memorized.

A. You are a very fair questioner.

MR. MORIARTY: It's a good time for a break anyway.

MS. THOMPSON: It's a good time for a break.

MR. MORIARTY: Do you want him to review in that time?

MS. THOMPSON: Yes. And I am still I think well on schedule to finish before 11:00.

when he says outcomes are often suboptimal, I'm not I guess quite sure how to characterize that "often."

So, I would just make that clarification or that comment on that series.

I would agree with the fact that later on it says, "Patients who underwent surgery for urethral obstruction had the highest success rates." That's very definitive typically, right, because there is an obstructive process and if you release the obstruction the problem is solved. So, I would agree that that leads to very high success rates.

And last comment I would make is "Pain is the least successful." Pain is so multifactorial, it can be very difficult to treat pain. So, I would agree that that can be very challenging.

Q. Now, let's go to where you thought we were going to start, the "Tissue responses to mesh."

Is there anything in the paragraph titled "Inflammatory Reactions" that you disagree with or do you feel like you're qualified to opine

So, I think -- I mean, I guess it may. But they listed "Tetention" separately on bullet point No. 6, "Urinary tract obstruction."

Now, we are up to No. 9, "Pain with intercourse which in some patients may not resolve." That looks like it was not discussed or at least cited in the IFU from the earlier one. So, that's a new bullet point, which is not included in the earlier one.

I guess regarding our understanding of pain with intercourse and such, I think that was sort of understood or at least on the part of doctors who do a lot of vaginal surgery.

"Neuromuscular problems including pain in the groin and thigh." The earlier IFU, this may have reflected TVT, not TVT-O. So, maybe now the later IFU they are including some of the issues regarding the groin and thigh pain which, again, are more unique to the TVT-O.

I apologize. I don't remember exactly when the TVT-O was introduced. I want to say 2002-2003. Do we know? I don't remember. I don't know if Matt -- nobody knows.

MR. MORIARTY: That was before 2015.

"Revision surgeries may be necessary." Again, that's sort of understood. It's not spelled out in the earlier one. But, right, if there is problems, you may have to address them.

And, finally, "Prolene mesh may need to be removed in part or in whole." So, I guess that's actually probably reasonable to have in there as an adverse reaction and it's not in there in the earlier IFU.

Q. And would surgeons have generally known that significant dissection may be required to remove the device?

A. I think anybody putting it in would recognize that if it needs to be revised or removed in some way, it would require dissection.

Q. And then the following list of "Other Adverse Reactions." Are there any there that would have been new after 2004?

MR. MORIARTY: Objection. Do you mean discovered after 2004?

MS. THOMPSON: Discovered after 2004.

MR. MORIARTY: Thank you.

BY THE WITNESS:

A. No, not really.